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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,660

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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,660	Applicant(s) DARIO ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/3/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 11 are rejected under 35 U.S.C. 112, second paragraph, as indefinite by using relative terminology referencing an object that is variable (the specific weight of internal organs, blood, or other fluid). Ex parte Brummer, 12 USPQ2d 1653 (Bd. Pat. App. & Inter. 1989). Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). See MPEP 2173.05(b).

3. Claims 3-5, 9, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 3 recites the limitation "the internal ones" in line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 4 recite the limitation "the ball" in line 2. Claims 9 and 12 recite the limitation "the ball" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 10 recite the limitation "radio-opaque locator floating relative to internal organs, blood, or other fluids present at the surgical site". A claim directed to or including within its scope a human being will not be considered to be patentable

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subject matter under 35 USC 101 (1077 O.G. 23, April 21, 1987). *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 18 USPQ2d 1677 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 6,248,088).

Regarding claim 10, Yoon discloses an organic fluid absorbing plug (16) for surgical use, the plug comprising an elongated body constructed of a material having haemostatic properties, the body connected to a radio-opaque locator (22).

Regarding claim 11, Yoon discloses the locator (22) comprises at least one ball and is connected to the plug by a wire (Fig. 7).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 6,248,088) in view of Reynolds et al (US 6,673,080).

Regarding claim 1, Yoon discloses a surgical device for removing organic fluids from a body cavity, the device comprising an absorbing plug (16), a tubular body (28)

suitable for slidably housing the plug, and a plunger (30) slidably engageable in the tubular body so as to push the plug outside thereof and place it at the surgical site (col. 4, ln. 49-60), the tubular body and plunger having a distal end and a proximal end, wherein the plug is connected to a radio-opaque locator (22). Yoon discloses the removal of the plug but fails to disclose the method and means of removal (col. 3, ln. 52-54). Yoon fails to disclose that at the distal end of the plunger, a handle is provided for gripping the locator for recovering the plug after use by retracting the plunger inside the tubular body. Reynolds et al. disclose providing a handle (30) for gripping and recovering material by retracting a plunger inside a tubular body (Fig. 1; col. 2, ln. 30-35). Therefore, it would have been obvious to one of ordinary skill in the art to have provided the handle as taught by Reynolds et al. in the device of Yoon in order to provide a means for removing the plug from the body.

Regarding claim 2, Yoon discloses the locator (22) comprises at least one ball and is connected to the plug by a wire (Fig. 7).

Regarding claim 3, Yoon does not disclose the size of the locator relative to the tube. However, it would have been obvious to one of ordinary skill in the art to have made the locator smaller than the inner dimensions of the tubular body so the locator may pass through the tubular body during insertion and removal of the plug.

Regarding claims 4 and 5, Yoon fails to disclose a loop at the distal end of the plunger. However, Reynolds et al. disclose that it is well-known to retrieve material from within the body using a loop at the end of a plunger to grasp and retract the material so that it may be extracted from the body. Reynolds et al. disclose the loop is formed by a relatively thin plate bent and connected at its ends to the distal end of the stem of the plunger (Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art

to have provided a loop for grasping the locator as suggested by Reynolds because it is a well-known structure used in the retrieval of foreign objects from the body. It also would have been obvious to one of ordinary skill in the art to make the loop generally wider than the ball so that the loop would fit around the ball because otherwise the loop could not function to retrieve the plug.

Regarding claim 6, Reynolds et al. disclose at the proximal end of the tubular body and of the stem, a handle is provided for actuating axial sliding of the stem in one direction or the other as a result of corresponding pressure actions exerted simultaneously in opposite directions on the handle (Fig. 1; col. 6, ln. 21-35).

Regarding claim 7, Reynolds et al. disclose the handle is of a ring type so as to allow engagement with the fingers of a user (Fig. 1).

Regarding claim 8, Reynolds et al. disclose that at the proximal end of the tubular body, a pair of handle rings are provided, generally diametrically opposite to and coplanar with one another, whereas at the proximal end of the stem, a handle ring is provided, generally coplanar thereto. (Fig. 1)

Regarding claim 9, Yoon discloses that the plug is preferably white in color to provide contrast with the surrounding tissue (col. 5, ln. 5-7).. Yoon however fails to disclose the color of the locator or "ball" surface. It would have been obvious to one of ordinary skill in the art to have also made the locator white or colored with a relatively light color to provide contrast with the surrounding tissue and fluids as suggested by Yoon.

3. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon.

Regarding claim 12, Yoon discloses that the plug is preferably white in color to provide contrast with the surrounding tissue (col. 5, ln. 5-7). Yoon however fails to

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disclose the color of the locator or "ball" surface. It would have been obvious to one of ordinary skill in the art to have also made the locator white or colored with a relatively light color to provide contrast with the surrounding tissue and fluids as suggested by Yoon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L. H./
Examiner, Art Unit 3734

jlh
4/10/08

/Todd E Manahan/

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Supervisory Patent Examiner, Art Unit 3731